UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Bristol-Myers Squibb Company,

Plaintiff,

v.

Nanocopoeia, LLC,

Defendant.

Case No. 22-cv-1283 (KMM/JFD)

ORDER

Since 2006, Plaintiff Bristol-Myers Squibb Company has manufactured Sprycel, a drug that is used to treat certain types of leukemia. Sprycel contains the active ingredient dasatinib in the crystalline monohydrate form. Bristol-Myers has two patents that claim the crystalline form of dasatinib: the '725 patent and '103 patent.[1] Defendant Nanocopoeia, a specialty pharmaceutical company based in Minneapolis, [redacted]. Bristol-Myers filed this patent infringement action, asserting that if Nanocopoeia's drug is approved, it would infringe Bristol-Myers' patents. By filing this case, Bristol-Myers triggered an automatic thirty-month stay on FDA approval of Nanocopoeia's drug. Nanocopoeia now moves for judgment on the pleadings, seeking dismissal of Bristol-Myers' infringement claims regarding the two patents covering the crystalline form of dasatinib, and a judgment of non-infringement on

[1] The full title of the patents at issue are United States Patent No. 7,491,725 and United States Patent No. 8,680,103. Bristol-Myers also alleges infringement of United States Patent No. 8,242,270, but that patent is not at issue in this motion.

the corresponding counterclaims that Nanocopoeia asserted against Bristol-Myers. For the reasons discussed below, the motion is **DENIED.**

BACKGROUND

Drug manufacturers obtain FDA approval through one of three types of applications: (1) a full New Drug Application ("NDA") if the drug has not yet been approved; (2) an Abbreviated New Drug Application ("ANDA") for a generic version of an already approved drug; and (3) a "505(b)(2) NDA" for a new formulation of an already approved drug. *See generally* 21 U.S.C. § 355. [redacted] [Nanocopoeia Mem. 8, Dkt. No. 73.]

Nanocopoeia's drug is not yet on the market, so this case involves allegations of hypothetical infringement under the Hatch-Waxman Act. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282, to provide a framework for the introduction of generic versions of previously approved drugs. *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 227 (3d Cir. 2013). The Act sought to strike a balance between incentivizing the development of new drugs by protecting patent holders who took on the risk of developing those drugs, and allowing competitors to bring low-cost alternatives to the market by making it easier, and faster, for them to secure FDA approval. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008).

Addressing those competing interests required compromises. The Act authorized patent term extensions for patent holders who lost time waiting for initial FDA approval of their drugs, *see* 35 U.S.C. § 156, but it allowed manufacturers seeking approval for a generic

version or new formulation of an already approved drug to start the FDA approval process before the initial patent expires, *see id.* at § 271(e)(1), and to rely on certain data provided in the NDA for the approved drug to make the application process a little less onerous, *see* 21 U.S.C. § 355(b)(2).

When an applicant files an ANDA or 505(b)(2) NDA, it must certify that its proposed drug will not infringe a current drug patent. It can do so by certifying that the listed drug is not patented, the patent has expired, or that the patent itself is invalid or won't be infringed by the new drug. *See Bayer AG v. Elan Pharm. Rsch. Corp.*, 212 F.3d 1241, 1244 (Fed. Cir. 2000) ("*Elan Pharm.*") (describing types of certifications); *see also* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV) (for ANDAs) and *id.* at § 355(b)(2)(A)(i)–(iv) (for 505(b)(2) NDAs). If the applicant certifies that the patent for the listed drug is invalid or won't be infringed by the proposed drug, but the owner of that patent disagrees and files an infringement suit within 45 days, the Hatch-Waxman Act triggers an automatic thirty-month stay on FDA approval of the new drug.[2] 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

In this way, the Hatch-Waxman Act makes the very act of filing an ANDA or 505(b)(2) NDA a technical or "artificial" act of infringement for purposes of vesting jurisdiction with the district court, so that the court can engage in the infringement analysis before the drug is approved and enters the market. *See Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (explaining that this artificial infringement theory is

[2] More specifically, the filing of an infringement action suspends FDA approval of the proposed drug "until the earliest of the expiration of the patent, judicial resolution of [the question of infringement,] or thirty months from the receipt of notice." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

meant to create "case or controversy jurisdiction"). But once jurisdiction is established by the "artificial" act of infringement, the inquiry of whether the patent will actually be infringed by the proposed drug "is determined by traditional patent infringement analysis." *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365–66 (Fed. Cir. 2003). The plaintiff patent owner "still carries the burden" to show that the defendant's product would infringe its patents. *Id.* And because the drug is not yet on the market, the infringement inquiry under the Hatch-Waxman Act involves a "hypothetical case that asks the factfinder to determine whether the drug that will be sold upon approval of the [application] will infringe the asserted patent." *In re Brimonidine Pat. Litig.*, 643 F.3d 1366, 1377 (Fed. Cir. 2011). The court must determine whether, if the proposed drug was approved and manufactured based on the specifications provided in the defendant's ANDA or 505(b)(2) NDA, it would infringe the plaintiff's patents. *Elan Pharm.*, 212 F.3d at 1248–49.

In this case, Nanocopoeia filed [redacted] vested case-or-controversy jurisdiction with the Court, and now this Court's task is to determine whether the drug envisioned by Nanocopoeia's NDA will infringe Bristol-Myers' patents.

[3] [redacted]

DISCUSSION

Nanocopoeia moved for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). In a patent case, the law of the regional circuit dictates the standard of review. *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1342–43 (Fed. Cir. 2019). Federal Circuit law applies to the extent a court must determine any substantive patent issue in ruling on that motion. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803 (Fed. Cir. 2000).

To be entitled to judgment on the pleadings, Nanocopoeia must establish that "no material issue of fact remains to be resolved" and that it is "entitled to judgment as a matter of law." *Poehl v. Countrywide Home Loans, Inc.*, 528 F.3d 1093, 1096 (8th Cir. 2008) (quotation omitted). This Court must accept factual allegations in the complaint as true and draw all reasonable inferences in favor of Bristol-Myers, as the non-moving party. *Nat'l Car Rental Sys., Inc. v. Comput. Assocs. Int'l, Inc.*, 991 F.2d 426, 428 (8th Cir. 1993). The Eighth Circuit permits district courts to consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "necessarily embraced by the pleadings" when ruling on a motion for judgment on the pleadings. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

Bristol-Myers does not need to "prove its case [of infringement] at the pleading stage." *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012). The question raised by this motion is not whether Bristol-Myers will "ultimately prevail" on its claim of patent infringement, but whether, from the face of the pleadings,

Nanocopoeia is entitled to a judgment of non-infringement as a matter of law. *See id.* "The standard is strict." *Nat'l Car Rental*, 991 F.2d at 428.

I. Procedural Challenges to the Motion

Bristol-Myers raises several arguments that suggest the Court should deny Nanocopoeia's motion on procedural grounds, without reaching the merits. As explained below, none of these arguments carries the day. First, Bristol-Myers appeared to argue that it can survive a motion for judgment on the pleadings in the Hatch-Waxman Act context simply by pleading the elements of artificial infringement, and that this Court should allow the particularized theory of infringement to arise later through discovery. [Bristol-Myers Squibb Opp'n. 20–21, Dkt. No. 87.] But the "limited, technical, and artificial cause of action" Congress created through the Hatch-Waxman Act was not intended to insulate patent holders from Rule 12 challenges; rather, its purpose is to vest jurisdiction "so that courts could promptly resolve infringement" disputes before the product entered the market. *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1376–77 (Fed. Cir. 2012); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (describing the "creation of a highly artificial" cause of action to "enable the judicial adjudication" of the ultimate infringement dispute in hypothetical infringement cases).

The creation of an "artificial" cause of action "only for jurisdictional purposes" does not disturb the plaintiff's burden to prove infringement, *Ferring B.V.*, 764 F.3d at 1408, nor does it take away district courts' ability to grant judgment on Rule 12 motions if they are able to find noninfringement as a matter of law. Bristol-Myers' contrary suggestion runs headlong into the numerous examples of district courts granting Rule 12(c) motions and

entering judgments of noninfringement in the hypothetical infringement context under the Hatch-Waxman Act. *E.g.*, *Par Pharm., Inc. v. Luitpold Pharms., Inc.*, No. 16-cv-02290 (WHW)(CLW), 2017 WL 452003, at *1 (D.N.J. Feb. 2, 2017); *Almirall, LLC v. Torrent Pharms., Ltd.*, 548 F. Supp. 3d 443, 446 (D. Del. 2021); *Bayer Schera Pharma AG v. Sandoz, Inc.*, 741 F. Supp. 2d 541, 543 (S.D.N.Y. 2010), *Biogen Int'l GmbH v. Banner Life Scis. LLC*, 424 F. Supp. 3d 303, 304 (D. Del. 2020); *Impax Lab'ys, Inc. v. Zydus Pharms. USA, Inc.*, Civil Action No. 17-13476, 2018 WL 6259244, at *1 (D.N.J. Nov. 29, 2018). Such a position is even more untenable in light of Federal Circuit decisions affirming judgments of noninfringement on the pleadings in this context. *See, e.g.*, *Biogen Int'l GmbH v. Banner Life Scis. LLC*, 956 F.3d 1351, 1353 (Fed. Cir. 2020); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1317 (Fed. Cir. 2012). Patent holders may not dodge judgment on the pleadings merely by pleading what is statutorily required to vest a court with jurisdiction over an act of artificial infringement. To the extent Bristol-Myers proffered such a position, it is readily rejected.

Second, Bristol-Myers contended in its briefing[4] that this Court may not consider documents attached to, and necessarily embraced by, the pleadings for the truth of the matters asserted therein. [Bristol-Myers Opp'n 21–23, Dkt. No. 87.] Bristol-Myers acknowledges, as it must, the well-established and uncontroversial principle in the Eighth Circuit that district courts may consider documents "necessarily embraced" by the pleadings when evaluating a Rule 12(c) motion. *Porous Media Corp,* 186 F.3d at 1079. However, Bristol-Myers points to a recent Eighth Circuit case rejecting an argument that a court could

[4] At the hearing, Bristol-Myers wisely conceded, or at least chose not to pursue, this argument when the Court raised it.

dismiss a complaint on qualified immunity grounds by considering, and accepting as truth, the narrative account contained in a police report drafted by the defendant. *See LeMay v. Mays*, 18 F.4th 283, 288–89 (8th Cir. 2021). Accordingly, Bristol-Myers argues that this Court may not look at the contents of documents integral to, and necessarily embraced by, the pleadings when ruling on this motion: [redacted] and Bristol-Myers' patents at issue. That cannot be so.

No party disputes the authenticity of these documents, nor does either party dispute their contents (even if the parties dispute the proper *interpretation* of those contents). The patents and pending FDA application are legally operative documents more akin to the contracts considered by the Eighth Circuit in *Zean v. Fairview Health Services*, 858 F.3d 520, 526 (8th Cir. 2017), for the truth of their contents, than the contested, self-serving police report at issue in *LeMay*. And besides being undisputedly authentic records, the patents at issue and specifications in the NDA "dominate" the infringement analysis. *Ferring B.V.*, 764 F.3d at 1408. So, of course this Court must consider those documents in infringement cases like this where they are necessarily embraced by the pleadings. *See also In re Brimonidine Pat. Litig.*, 643 F.3d at 1377 (describing the infringement action under the Hatch-Waxman Act as a "hypothetical case that asks the factfinder to determine whether the drug that will be sold upon approval *of the ANDA* will infringe *the asserted patent*") (emphasis added). Given that a court's very task in determining a question of hypothetical infringement is to compare the language in the defendant's ANDA or 505(b)(2) NDA to that in the plaintiff's patents, the Court would be abdicating its responsibilities by accepting Bristol-Myers' argument. *See AstraZeneca Pharms. LP*, 669 F.3d at 1378 & n.5 (decision by the Federal Circuit holding that

it was not error for the district court to consider statements in the defendants' ANDA filings when ruling on their motions to dismiss).

In rejecting the positions taken by Bristol-Myers on this point, the Court finds instructive a decision by Judge Leonard Stark before he was elevated to the Federal Circuit. *See Almirall, LLC v. Torrent Pharms., Ltd.*, 548 F. Supp. 3d 443, 448 (D. Del. 2021). In *Almirall,* Judge Stark admonished the plaintiff for its "incorrect procedural arguments"—the same ones advanced by Bristol-Myers in this case—that the court may not grant a Rule 12(c) motion in a hypothetical infringement case or that it would be "improper for the Court to consider portions of [the defendant's] ANDA" in ruling on such a motion. *Id.* at 448–49. For the same reasons relied upon by Judge Stark in *Almirall* (although likely less eloquently restated), this Court rejects Bristol-Myers' incorrect procedural arguments.

II. The Motion's Merits

Turning to the merits of Nanocopoeia's motion for judgment of non-infringement on the pleadings, the parties genuinely dispute whether [redacted] and the Court finds that this dispute of material fact precludes judgment at this stage.

There are two types of hypothetical infringement cases: those in which the specifications in the defendant's NDA[5] directly answer the question of infringement, and those in which the NDA specifications do not. *Ferring B.V.*, 764 F.3d at 1408–09. For instance, in *Elan Pharm.*, where the specifications in the defendant's ANDA required a

[5] For ease of reference, [redacted]

surface area outside of the range claimed by the plaintiff's patent, the Federal Circuit held that the specifications resolved the infringement question and affirmed a judgment of non-infringement. 212 F.3d at 1249; *see also In re Brimonidine Pat. Litig.*, 643 F.3d at 1377 (reversing judgment of infringement where plaintiff's patent required a pH of 7.0 or greater but the specifications in defendant's ANDA limited it to manufacturing a product with a maximum 6.7 pH).

Whether the NDA specifications directly answer the question of infringement matters because it determines, in part, the type of evidence district courts may consider in assessing the merits of the claim. Where the specifications in the defendant's NDA directly resolve the infringement question by defining a proposed drug "in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim," *Ferring*, 764 F.3d at 1408, then the district court's analysis "begins and ends" with the NDA, *Par Pharm., Inc. v. Eagle Pharms., Inc.*, 44 F.4th 1379, 1384 (Fed. Cir. 2022). The reason the Federal Circuit allows the NDA specifications to control the analysis when the specifications answer the infringement question is because defendants are legally bound to the specifications provided in their NDA. *See Elan Pharm.*, 212 F.3d at 1249–50 (discussing the significant civil and criminal penalties if a manufacturer does not comply with the release specifications listed in its application to the FDA). Accordingly, if a defendant would not infringe the plaintiff's drug by manufacturing a drug in compliance with the specifications outlined in its NDA, then there is no need to consider other evidence, and a judgment of noninfringement is appropriate.

But in the second type of case, where the NDA specifications for the proposed drug do not directly and completely answer the infringement question, then courts are permitted to consider other relevant evidence, such as tests of actual drug samples and expert testimony, evidence obviously inappropriate for consideration at the Rule 12 motion stage. *See Ferring B.V.*, 764 F.3d at 1409 (endorsing consideration of relevant evidence, including batch data and drug composition samples when a specification does not resolve the infringement analysis in the first instance). In *Glaxo, Inc. v. Novopharm, Ltd.*, for instance, the Federal Circuit approved the district court's consideration of "other pertinent evidence provided by the parties" in addition to the ANDA because the specifications alone did not answer whether the proposed drug would infringe. 110 F.3d at 1570. Although the defendant's ANDA specified the crystalline form of an active ingredient at a certain purity, it did not resolve whether a different crystalline form that was claimed by the plaintiff's patents could be present. *Id.*

A. A Genuine Factual Dispute

Here, the parties dispute whether [redacted]. [redacted] the parties agree that it infringes Bristol-Myers' patents. [redacted], then it does not infringe. Nanocopoeia maintains that [redacted] Bristol-Myers disagrees.

Nanocopoeia has pointed to no case where a district court granted judgment on the pleadings when the parties genuinely dispute whether the specifications in the defendant's

NDA directly answer the infringement question. Certainly, Nanocopoeia has cited instances in which courts have granted judgments of noninfringement in the Hatch-Waxman Act context, but those took place at later stages, such as at summary judgment or after a bench trial. *See, e.g.*, *Bayer AG v. Elan*, 64 F. Supp. 2d at 1300, *aff'd*, 212 F.3d 1241 (Fed. Cir. 2000) (summary judgment); *Par Pharm., Inc. v. Eagle Pharms. Inc.*, Civil Action No. 18-0823-CFC-JLH, 2021 WL 3886418, at *10 (D. Del. Aug. 31, 2021), *aff'd*, 44 F.4th 1379 (Fed. Cir. 2022) (bench trial).

The Court's own research has revealed only three categories of cases where district courts have entered judgment on the pleadings in the Hatch-Waxman Act context, all of which are distinct from the circumstances presented here. In one such category, the plaintiff has conceded that the specifications in the defendant's ANDA or 505(b)(2) NDA directly resolve the question of infringement and agreed that if the defendant actually complied with those specifications, the resulting product would not infringe. *See, e.g.*, *Par Pharm., Inc. v. Luitpold Pharms., Inc.*, No. 16-cv-02290 (WHW)(CLW), 2017 WL 452003, at *6–7 & n.4 (D.N.J. Feb. 2, 2017) (plaintiff admitted that drug formulation in defendant's ANDA would not infringe its patents but argued that at some point the FDA would require the defendant to amend its ANDA specifications); *Impax Lab'ys, Inc. v. Zydus Pharms. USA, Inc.*, Civil Action No. 17-13476, 2018 WL 6259244, at *2 (D.N.J. Nov. 29, 2018) (plaintiff conceded noninfringement based on the defendant's ANDA specifications but contended that "sometime in the future, and in some unknown way" the defendant would change its ANDA formulation); *see also Cumberland Pharms. Inc. v. InnoPharma, Inc.*, C.A. No. 12-618-LPS, 2013 WL 5945794, at *2 (D. Del. Nov. 1, 2013) (plaintiff's patents covered formulations

"free from a chelating agent," yet its complaint acknowledged that the defendant's ANDA specified a product containing a chelating agent). Bristol-Myers has made no such concession in its briefing, at the hearing, or in its complaint.

The second category of relevant decisions encompasses method-of-use cases in the generic drug context, where the defendant seeks to market a generic drug for a different use than that claimed by the plaintiff's patents. *See, e.g.*, *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1326 (Fed. Cir. 2012) (affirming judgment of noninfringement on the pleadings where the defendant sought approval to market a generic form of the plaintiff's drug solely for contraceptive use, and the plaintiff's patents claimed a method of use consisting of a combination of anti-androgenic, anti-aldosterone, and contraceptive effects). This category plainly does not apply here.

The third category of cases where courts have granted motions for judgment of noninfringement on the pleadings in the Hatch-Waxman Act context have involved disputes of legal, not factual, questions. *See, e.g.*, *Almirall*, 548 F. Supp. 3d at 448 (granting judgment on the pleadings where parties agreed that the defendant's NDA did not literally infringe the plaintiff's patent, and the remaining dispute concerned the application of argument-based prosecution history estoppel, which the court noted was ultimately a legal determination); *see also In re Bendamustine Consol. Cases*, Civil Action No. 13-2046-GMS, 2015 WL 1951399, at *1–2 (D. Del. Apr. 29, 2015) (granting judgment on the pleadings where plaintiff's patents claimed compositions of a certain type of alcohol, the defendants' ANDA products did not contain that type of alcohol, and the infringement inquiry was controlled by whether the plaintiff's doctrine-of-equivalent arguments were barred by the disclosure-dedication rule, a

"question of law"). But here, [redacted] and a hotly debated one.

Certainly, judgment on the pleadings is not confined to these three types of cases. But this Court is presented with a genuine dispute of material fact, and no precedent in which a court has granted the relief sought by the defendant in similar circumstances. This Court will not be the first. The fact that neither Nanocopoeia nor this Court could find a case [redacted] suggests that granting judgment of noninfringement in such circumstances is inappropriate.

B. The Disputed Specifications

Of course, this Court must not simply accept Bristol-Myers's argument that the parties dispute [redacted] to determine if the dispute is genuine. Otherwise, patent holders could defeat a Rule 12(c) or 12(b)(6) motion merely by claiming [redacted]

[redacted] [*Id.*]

[redacted] This is because the federal regulations define "specification" as "the quality standard (i.e., tests, analytical procedures, and acceptance criteria) provided in an approved NDA or ANDA" that "confirm[s] the quality of drug substances, drug products . . . and other materials used in the production of a drug." 21 C.F.R. § 314.3(b). This definition also expressly states that this term includes "numerical limits, ranges, or other criteria for the tests described." *Id.*

[redacted]

[redacted]

[redacted] *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 477 F. Supp. 3d 306, 317 (D. Del. 2020), *aff'd sub nom. Bristol-Myers Squibb Co. v. Sigmapharm Lab'ys, LLC*, 858 F. App'x 359 (Fed. Cir. 2021).

[redacted] [*Id.* at 41.]

This exchange highlights that there is a genuine dispute of material fact precluding judgment on the pleadings. Questions involving what a person of ordinary skill in the art would understand a term to mean are questions for claim construction. *E.g.*, *Oil-Dri Corp. of Am. v. Nestle Purina Petcare Co.*, Case No. 15 C 1067, 2018 WL 4216627, at *5 (N.D. Ill. Sept. 5, 2018). But district courts have "repeatedly held" that if a court must engage in claim construction to "resolve a motion to dismiss or motion for judgment on the pleadings, the motion should be denied, because this type of analysis is inappropriate at the pleading stage." *Anglefix Tech, LLC v. NuVasive, Inc.*, No. 13-CV-983-BEN(RBB), 2014 WL 197736, at *2 (S.D. Cal. Jan. 14, 2014) (denying motion for judgment on the pleadings on this basis and collecting cases).

[redacted]

[redacted] These are quintessential factual disputes that are not only genuine but also material—disputes that are inappropriate for the Court to resolve on the pleadings. The standard for granting judgement on the pleadings is strict: it is not appropriate unless Nanocopoeia clearly establishes that "no material issue of fact remains to be resolved" and that the moving party is "entitled to judgment as a matter of law." *Nat'l Car Rental*, 991 F.2d at 428. Nanocopoeia has failed to meet its burden here, so the Court must deny its motion.[7]

CONCLUSION

The Court hears, and understands, Nanocopoeia's frustrations in this dispute. [redacted]

[7] The Court agrees with Nanocopoeia that some of Bristol-Myers' efforts to highlight factual disputes cross into the type of speculative arguments the Federal Circuit has repeatedly instructed courts to reject, *i.e.*, arguments premised on conjecture that a defendant might, despite its representations to the FDA, nevertheless sell a product that does not comply with the specifications outlined in its NDA. *See In re Brimonidine*, 643 F.3d at 1377–78 (finding that the "district court erred by assuming that [the defendant] would manufacture a drug outside of the parameters of the ANDA" because it is legally bound by such representations); *see also Warner-Lambert*, 316 F.3d at 1364; *Elan Pharm.*, 212 F.3d at 1249; *Eagle*, 44 F.4th at 1384. [redacted] While such an argument can be readily rejected under this line of Federal Circuit authority, Bristol-Myers' other arguments are different in kind, [redacted]

[redacted]

In the abstract, it may appear counter to the spirit of the Hatch-Waxman Act to deny Nanocopoeia's motion for judgment of noninfringement [redacted]. But Congress performed the herculean task of weighing such policy considerations when it struck the balance it chose for the Hatch-Waxman Act, and it is not this Court's job to second guess that balance but to apply it.

In applying the provisions of the Hatch-Waxman Act here and the standards governing motions for judgment on the pleadings, this Court finds that judgment on the pleadings is inappropriate in this case. Judgment on the pleadings is not warranted where a genuine dispute of material fact precludes the Court from finding [redacted] But the Court's response to Nanocopoeia's arguments should not necessarily be interpreted as "no," but perhaps as "not yet." This litigation will benefit from claim construction and the consideration of extrinsic evidence. For those reasons, the Court denies Nanocopoeia's motion and allows this case to proceed.

ORDER

For the foregoing reasons, **IT IS HEREBY ORDERED** that Nanocopoeia's Motion for Judgement on the Pleadings [Dkt. No. 72] is **DENIED.**

Date: March 24, 2023

s/Katherine Menendez
Katherine Menendez
United States District Judge